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TITLE: CIMIT/TATRC Symposium on Developing a Plug-and-Play Open Networking Standard for the Operating Room of the Future

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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**13. ABSTRACT (Maximum 200 Words)**

The ORF PnP Symposium was held on May 24-25 2004 at CIMIT in Cambridge, MA. Eighty-four clinical and technical thought leaders met and explored the context, issues, challenges, and potential rewards of standardizing medical device plug-and-play (PnP) interoperability in the Operating Room of the Future (ORF). Key topics included: identifying issues that have impeded prior efforts at standardization; identifying current efforts that can be incorporated into a standardization framework; identifying stakeholders; deciding if ORF PnP standards should include control of other devices or be limited to data communication; selecting perioperative devices that should be included in the proposed standard; and identifying medico-legal and regulatory issues that must be addressed to permit safe control of medical devices. The symposium brought together diverse stakeholders for the first time, enabling the richness of dialogue that was necessary to reach consensus on proceeding with an ORF PnP initiative. It led to a virtual web of collaborations and strong consensus to develop a program, and a host of follow-on activities, including a second plenary meeting hosted by the FDA with participation from NIST and the NSF, and focus group sessions at medical society meetings (STA and SAGES) and in clinical departments.

**14. SUBJECT TERMS**
Medical device, plug-and-play, interoperability, communication bus, Patient safety, device control, operating room, health care

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# Table of Contents

## Report on ORF PnP Symposium Held on May 24-25, 2004
## Award Number W81XWH-04-1-0592

### Introduction

Medicine – and specifically, the operating room environment – has not had the benefit of standardized control and communication systems. As a result, many self-evident improvements – such as seamless data communication, medical device integration, remote device actuation, and distributed closed-loop control systems – have been precluded, and safety and economic benefits have not been realized. Funding was sought for a symposium to begin the process of defining technical and clinical requirements for a bus-independent Plug-and-Play (PnP) standardization framework for medical devices in the Operating Room of the Future (ORF). To effectively define these requirements and set an agenda for standards development required convening a group of medical device producers, clinical users, facility biomedical engineers, governmental regulators (including the FDA), and standards-writing experts. The two-day symposium was organized to 1) educate the participants in relevant technology, the regulatory picture, and clinical practice; 2) provide a forum for discovery of important issues and barriers to implementing PnP in the ORF; and 3) organize participants' contributions to refine the concepts, establish a consensus to move forward, and generate material to serve as the foundation for the proposed ORF PnP standard.

### Report

The ORF PnP Symposium was held on May 24-25 2004 at CIMIT in Cambridge, MA. A group of 84 clinical and technical thought leaders – medical device manufacturers/producers, clinical users, facility biomedical engineers, governmental regulators, and standards-writing experts (including 43 clinical and academic device "users", 37 industry participants from 21 companies, 3 FDA staff, and the TATRC sponsor) – met and enthusiastically discussed the context, the issues, the challenges, and the potential rewards of setting an agenda for standards development for medical device interoperability in the ORF. The symposium brought together these diverse groups in the same room for the first time, and enabled the kind of dialogue that was necessary to reach consensus on moving ahead with an ORF PnP initiative. The agenda (Appendix A) included a series of speakers to educate the group on interoperability issues, some brief informational presentations from industry, and an opportunity to define high level requirements in smaller group breakout sessions.

The following key points were addressed:

- Which issues have impeded prior efforts at such standardization? Which aspects of current efforts can be incorporated into a consensus standard?

- Who are the stakeholders? How can their issues be recognized?

- Should an ORF PnP standard include control of other devices, or be limited to real-time communication?

- Which preoperative devices should be included in the proposed standard?

- What medico-legal and regulatory issues must be addressed to permit safe control of medical devices?

Talks given at the symposium were videotaped and subsequently made available as streaming video on the CIMIT web site (www.cimit.org). Newcomers to the ORF PnP initiative are referred

to these talks as background, and there have been **2700** hits on these pages since they became available last October.

This symposium served as the major kick-off event for the ORF PnP initiative, and led to a series of related follow-up activities that have achieved a strong momentum for an ongoing effort. Chief among these was a second plenary meeting, hosted by the FDA on November 15-16 2004 at the CDRH facilities in Rockville, thus facilitating a direct dialogue with FDA staff about the regulatory framework for PnP. The FDA meeting had 75 attendees, one-third of whom had attended the May symposium (affirming their ongoing commitment to ORF PnP) and two-thirds of whom were new (thus expanding the involved stakeholder base). The attendees included 28 clinical and academic device "users", 32 industry participants from 22 companies, 10 FDA staff, 2 from TATRC, and one each from NSF and NIST.

As a result of initial work at the November meeting on defining clinical requirements, a series of focus group sessions were held at medical societies to gather clinical requirements for PnP in the ORF. These sessions were conducted at the Society for Technology in Anesthesia (STA) in January and at the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) in April, with a similar session for clinical engineers planned for the AAMI meeting (Association for the Advancement of Medical Instrumentation) in May. There is interest in conducting a focus group for DoD clinicians (from Walter Reed and the VA) in conjunction with TATRC in coming months.

A virtual web of collaborations has been created as a direct result of the May ORF PnP symposium. As illustrated in Figure 1, these collaborations include activities and relationships with Federal agencies; clinical, engineering, and IT societies; clinicians in the USA, Europe, and Japan; and integrated health delivery networks.

Collaboration Highlights:
- The Society for Technology in Anesthesia supported an ORF PnP focus group at their annual meeting in January, stated their ongoing official support of the work, and designated a PnP session at the next annual meeting in January 2006.
- The executive committee of the American Society of Anesthesiologists is assessing approaches to support the program.
- The OSEL division of the US FDA have become key partners in planning and hosting meetings, providing guidance on project strategic planning, and helping with methodology for developing user requirements.
- The National Institute of Standards and Technology has provided in-kind support by attending clinical focus groups and providing expert assistance in converting high-level clinical user requirements into engineering requirements.
- The National Science Foundation has facilitated collaboration with other NSF grantees working in related areas, and has encouraged the pursuit of future funding for ORF PnP through NSF.
- Kaiser Permanente has publicly stated its commitment to PnP in multiple venues, has been assisting with the analysis of clinical use cases, and has been providing strategic planning guidance.
- The "Integrating the Healthcare Enterprise" initiative of the Healthcare Information and Management Systems Society (HIMSS) has agreed to establish a domain for the OR, in order to assure interoperability of OR solutions in the broad healthcare environment.

These collaborations will fuel continued expansion of the support network for ORF PnP, greatly increasing the likelihood of completion of the program and acceptance of the standards.

As a result of both collaborations and exposure at national meetings, AAMI has published two articles on ORF PnP – one in the January issue of *AAMI News* and one as the cover article in the May/June issue of its peer-reviewed journal *Biomedical Instrumentation & Technology*. An interview with the PI appeared in the April *AAMI News,* and he was invited to speak at the AAMI Human Factors meeting in June.

To facilitate communication and to provide a forum for project activity, an ORF PnP web site was set up (www.orfpnp.org), as well as online interactive discussion forums for the four Working Groups that were established subsequent to the May symposium: 1) WG1: Clinical Requirements, 2) WG2: Regulatory/Legal, 3) WG3: Communication Architecture, and 4) WG4: User Interface Requirements. The email distribution list for program communication has grown to more than 350 names, as a result of contacts that came from the May symposium participants, supplemented through subsequent collaborations and meetings.

**Key Research Accomplishments**

- Establishment of an ORF PnP program with a diverse, committed stakeholder community
- Elicitation of high-level clinical requirements from anesthesiologists and surgeons
- Establishment of a working relationship with FDA that involves frequent interaction and committed participation in this effort
- Collaborations with NSF, NIST, and University of Pennsylvania to enhance the quality and effectiveness of ORF PnP subprojects

**Reportable Outcomes**

Meetings:

- October 22 2004 Meeting at ASA (20 attendees)
- November 15-16 2004 Meeting at FDA (75 attendees)
- January 13 2005 Focus Group Session at STA (50 attendees)
- January 28 2005 Meeting with IHE in Cambridge (18 attendees)
- February 15 2005 Informational Session at HIMSS (45 attendees)
- February 17 2005 for IHE Strategic Planning Committee at HIMSS (20 attendees)
- April 15 2005 Focus Group Session at SAGES (25 attendees)

ORF PnP Presentations:

- September 30 2004 at Scottsdale Institute seminar held at Partners HealthCare, Boston, MA
- October 5 2004 at Phillips Medical Systems, Germany
- October 8 2004 at 15th International Society of Computing in Anesthesia and Intensive Care, Toulouse, France
- November 16 2004 at HCMDSS workshop planning meeting, Washington DC
- January 21 2005 at Medtronic, Seattle, WA
- January 22 2005 at ASA committee on information technology, Phoenix, AZ
- February 17 2005 at IHE Strategic Development Committee at HIMSS
- March 9 2005 at University of Washington, Seattle, WA
- April 6 2005 at Philadelphia Society of Anesthesiologists
- April 7 2005 at Jefferson Medical College, Philadelphia, PA

Web Site:

- www.orfpnp.org established and maintained as major communication vehicle
- Online interactive forums provided for Working Groups and other communication

Manuscripts/Publications:

- January *AAMI News*: ORF PnP article
- April *AAMI News*: Interview with Julian Goldman *re* ORF PnP Program
- May/June *Biomedical Instrumentation & Technology*: ORF article
- May/June *Biomedical Instrumentation & Technology*: ORF PnP article

Funding Applications:

- Funded: CIMIT: $200K for first-year core support of the Principal Investigator (37.5%) and Project Manager (50%)
- Submitted: The Whitaker Foundation: $20K for Planning Conference for PnP Biomedical Engineering Lab
- Submitted: Partners Healthcare IS Research Council: $64K for Developing Formal Requirements-Engineering Methodology in Support of the ORF PnP Program
- In process: DoD SBIR Phase II extension for LiveData grant, to support application of their work to PnP Lab
- In process: TATRC: $720K over 3 years for ORF PnP project core support of the PI and Project Manager
- In process: NSF: $100K+ add-on to University of Pennsylvania application to apply embedded and hybrid systems modeling tools to medical devices in the ORF PnP Lab

Other:

- Julian M. Goldman, MD, nominated by Kaiser Permanente for HIMSS Physicians IT Leadership Award

## Conclusions

The ORF PnP kick-off symposium supported by TATRC and CIMIT has been highly effective in providing a platform to initiate an effective program to develop a standardization framework for medical device interoperability. The network of collaborators and stakeholders continues to expand, further confirming the relevance of the work.

## References

"Plug and Play" Connectivity Initiative Launched, *AAMI News* 40:1, January 2005 (Association for the Advancement of Medical Instrumentation).

Goldman JM, Schrenker RA, Jackson JL, Whitehead SF. Plug-and-Play in the Operating Room of the Future. *Biomedical Instrumentation & Technology* 39:3, May/June 2005.

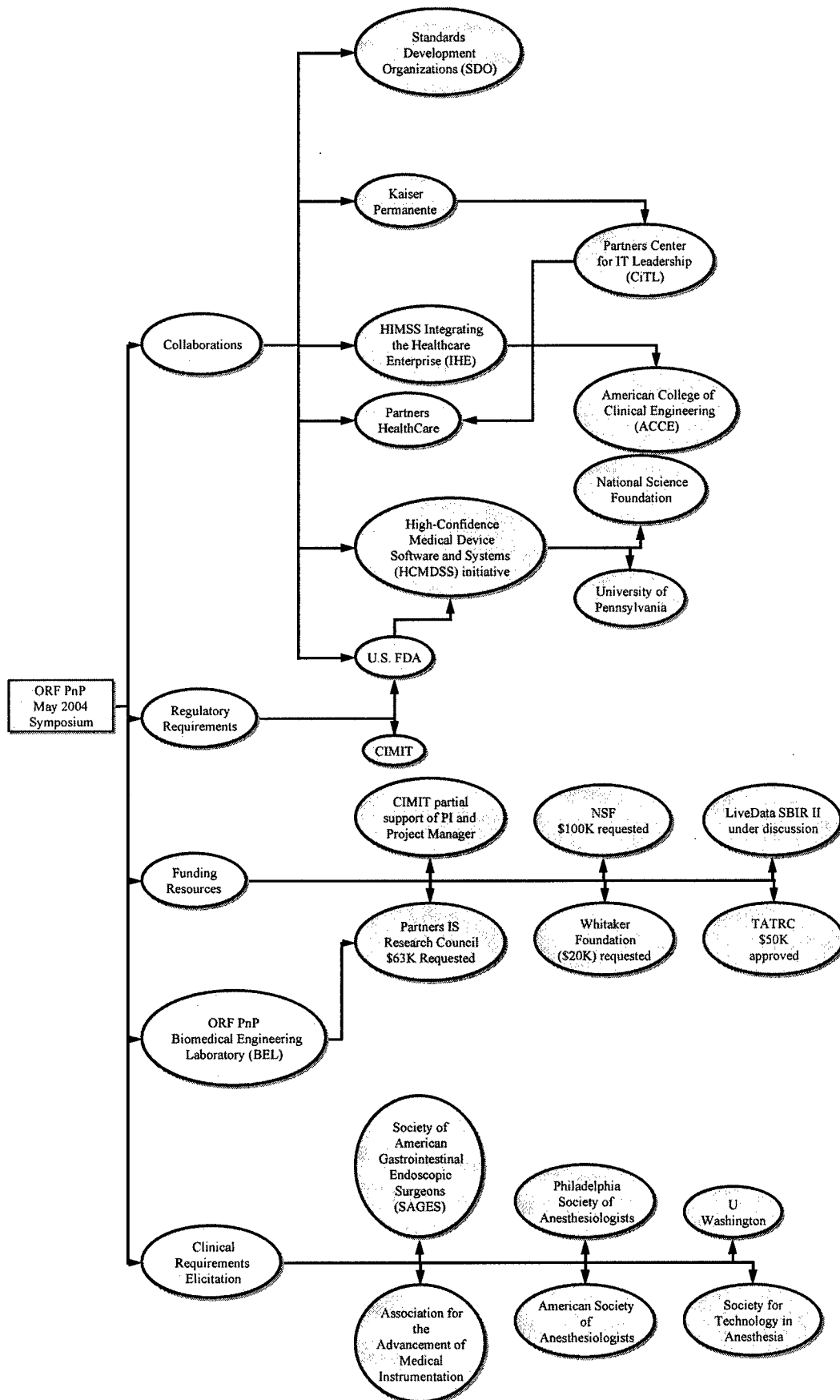Brady J. Inside the OR of the Future. *Biomedical Instrumentation & Technology* 39:3, May/June 2005.

**Figure 1**

## List of Appendices

A: May Symposium Agenda

B: May Symposium Roster by Institution/Organization

C: November Meeting Agenda

D: November Meeting Roster by Institution/Organization

E: STA Focus Group Announcement/Handout

F: SAGES Focus Group Announcement/Handout

G: AAMI Focus Group Announcement/Handout

H: Picture of Web Site Home Page

I: Picture of Forums Web Site Home Page

J: *AAMI News* PnP Article Reprint

K: *Biomedical Instrumentation & Technology* ORF & PnP Articles

**APPENDIX A**

# Operating Room
## of the Future

a CIMIT/TATRC Symposium
May 24-25, 2004

**Developing a Plug-and-Play Open Networking Standard**

# Monday, May 24

| | |
|---|---|
| 8:00 – 9:00am | Registration and Continental Breakfast |

## Session I

| | |
|---|---|
| 9:00 – 9:10 | Welcome<br>*Julian Goldman and Ron Marchessault, Co-Chairs* |
| 9:10 – 9:30 | Historical Overview of Equipment Standards in Healthcare<br>*John Hedley-Whyte, MD, Harvard Medical School* |
| 9:30 – 9:50 | Symposium Objectives<br>*Julian Goldman, MD, Massachusetts General Hospital* |
| 9:50 – 10:15 | Control Networks<br>*Holger Zeltwanger, CAN in Automation* |
| 10:15 – 10:30 | FDA Perspective on Device Integration<br>*Ann Graham, CRNA, MPH, FDA* |
| 10:30 – 10:55 | Clinical Vision:  What will plug-and-play bring to the OR of the Future?<br>*John Howse, MD, Kaiser Permanente* |
| 10:55 – 11:30 | Why Now?<br>*Jeff Elton, PhD, McKinsey & Company, Inc.* |

| | |
|---|---|
| 11:30 – 1:00pm | Networking Lunch  (Asgard Restaurant) |

## Session II

| | |
|---|---|
| 1:15 – 1:30pm | Federal Goals of Standardization in the OR of the Future<br>*Ron Marchessault, MBA, U.S. Army Telemedicine &*<br>*Advanced Technology Research Center (TATRC)* |
| 1:30 – 1:50 | The Business Case for ORF PnP Standardization<br>*Blackford Middleton, MD, Brigham and Women's Hospital* |
| 1:50 – 4:30 | Voice of Industry<br>*Brief presentations by manufacturers* |
| 4:30 – 5:00 | First Day Wrap-up<br>*Julian Goldman and Jeff Elton* |

| | |
|---|---|
| 6:00 – 9:00pm | Reception and Dinner  (Hotel@MIT) |

# Tuesday, May 25

7:30 – 8:00am      Continental Breakfast

## Session III

8:00 – 8:15am      Review of Day 1

8:15 – 8:40      Medical Systems Validation
*Sandy Weininger, PhD, FDA*

8:40 – 9:00      Information Displays of the Future for Anesthesiologists
[Clinical Application of Closed Loop Controllers]
*Dwayne R. Westenskow, PhD, University of Utah
Medical Center*

9:00 – 9:20      Medical Information Bus
*S. Mark Poler, MD, Geisinger Health System*

9:20 – 9:30      Set up for Breakout Sessions
Quick break

9:30 – 11:30      Breakout Sessions: Needs Analysis
***Facilitators:*** *Warren Sandberg, MD, PhD, Massachusetts
General Hospital*
*John Howse, MD, Kaiser Permanente*

11:30 – 11:45am      Break; Pick up box lunches

## Session IV

11:45 – 2:15pm      Working Lunch
Breakout Groups Report Back

2:15 – 3:00      Summarize; Plan Next Steps

3:00pm      Adjourn

# APPENDIX B

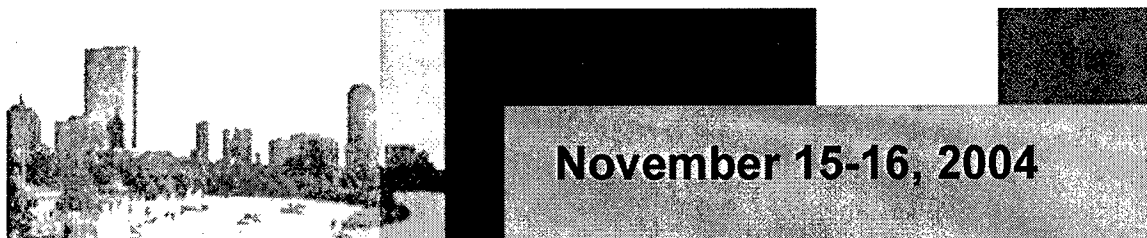## PnP Symposium Attendees Roster
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**November 15-16, 2004**

# Second Meeting of the ORF PnP Standardization Project
*A multidisciplinary project to develop standards for communication and control of medical devices in the OR of the Future*

This meeting will focus on:
**Developing Functional Requirements** and **Assessing the Regulatory Model**

Hosted by: **Food & Drug Administration**
9200 Corporate Blvd, Room 020B, Rockville, Maryland

## Monday, November 15

| | |
|---|---|
| 8:30 – 9:00am | Registration / Coffee |

| | |
|---|---|
| 9:00 – 9:30 | Welcome, Conference Overview, Current Status of ORF PnP Standardization Program<br>*Julian M. Goldman, MD*<br>Principal Investigator, ORF PnP Program<br>CIMIT/Massachusetts General Hospital |
| **9:30 – 12:00** | **WG1: Clinical Requirements**<br>*WG1 Leader: John Howse, MD, Kaiser Permanente* |
| 9:30 – 10:00 | Clinical Requirements of PnP Systems<br>*James C. Fackler, MD*<br>Director of Critical Care, Cerner Corporation<br>Associate Professor, Anesthesiology/CCM,<br>Johns Hopkins University School of Medicine |
| 10:00 – 11:00 | Breakout Session I: Identify Top Clinical Requirements & Clinical Use Scenarios<br>*Facilitators and Scribes TBA* |
| 11:00 – 12:00 | Groups Report Back: Consolidate Requirements |

| | |
|---|---|
| 12:00 – 1:00pm | Networking Lunch (sandwiches brought in) |

## Monday, November 15  (continued)

**1:00 – 5:00pm**    **WG2: Regulatory Requirements**
*WG2 Leaders: Jennifer A. Henderson, JD, MPH, CIMIT*
*Michael Husband, FDA*

**1:00 – 1:20**    Designing High-Assurance Complex Systems: Future Directions
*D. Helen Gill, PhD*
Director, Embedded & Hybrid Systems Program
National Science Foundation

**1:20 – 1:45**    Current and Future States of Device Systems
*Paul L. Jones, MSCE*
Senior Systems/Software Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
*Office of Science and Engineering Laboratories*

**1:45 – 2:15**    Regulatory Experience with Networked Medical Systems
*John Murray, MSEE*
Software & Electronic Medical Record ("Part 11") Compliance Expert
U.S. Food and Drug Administration
Center for Devices and Radiological Health, *Office of Compliance*

**2:15 – 2:45**    Future Models to Assure Safety and Effectiveness of ORF PnP
Interconnected Systems
*Brian Fitzgerald*
Acting Deputy Division Director
U.S. Food and Drug Administration
Center for Devices and Radiological Health
*Office of Science and Engineering Laboratories*

**2:45 – 3:00**    Break

**3:00 – 4:15**    Breakout Session II: Identify Top High-Level Regulatory Requirements
(Performance, Functional, and Interface) and Suggestions for Alternate
Approaches to Current Regulatory Framework
*Facilitators and Scribes TBA*

**4:15 – 5:00**    Groups Report Back: Consolidate Requirements
Wrap up

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Dinner on your own – network!

# Tuesday, November 16

| | |
|---|---|
| 7:30 – 8:00am | Coffee |

| | |
|---|---|
| 8:00 – 8:30 | Roles for Clinical Engineering in Specifying IT Requirements<br>*Rick Schrenker*<br>Systems Engineering Manager<br>Massachusetts General Hospital Dept of Biomedical Engineering |
| 8:30 – 9:00 | From Wishlist to QoS: The Process<br>*Todd Cooper*<br>Chair, IEEE 1073 General Committee |
| 9:00 – 9:30 | **WG3 Status Report: PnP System Architectures**<br>*WG3 Leaders: Bill Seitz, IXXAT Inc.*<br>*Jeff Robbins, LiveData Inc.* |
| 9:30 – 9:45 | Instructions to Breakout Groups<br>*Julian M. Goldman, MD*<br>*WG4 Leader: Dwayne R. Westenskow, PhD*<br>*University of Utah Medical Center* |
| 9:45 – 10:00 | Break |
| 10:00 – 11:00 | Breakout Session III:<br>IIIA: ORF PnP relationship to existing standards<br>IIIB: **WG4 – User Interface Requirements** |
| 11:00 – 12:00 | Groups Report Back: Consolidate Requirements |

| | |
|---|---|
| 12:00 – 1:00pm | Networking Lunch (sandwiches brought in) |

| | |
|---|---|
| 1:00 – 2:00 | Consolidate Requirements for WG1, WG2, WG4 – to be sent to WG3 for review and response |
| 2:00 – 3:00 | Defining the Scope of the ORF PnP Project: near- and long-term objectives of project plan<br>Next Steps<br>*Julian M. Goldman, MD* |
| 3:00 | Adjourn |

**Contact:** Sue Whitehead, ORF PnP Project Coordinator
617-768-8760 swhitehead@partners.org

# APPENDIX D

## Nov 2004 PnP Standards: Attendees    By Institution/Company

| Institution/ Company | Name | Email |
|---|---|---|
| B. Braun Medical Inc. | Melanson, Eric | eric.melanson@bbraun.com |
| Baxter Healthcare Corporation | Wilkinson, Bob<br>De Joya, Manuel | bob_wilkinson@baxter.com<br>manuel_de_joya@baxter.com |
| Brigham & Women's Hospital | Jackson, Jennifer | jljackson@partners.org |
| Broadlane | Traskos, Sabrina | sabrina.traskos@broadlane.com |
| Cambridge University Hospitals NHS Foundation Trust | Divanis, George | george.divanis@addenbrookes.nhs.uk |
| CAN in Automation | Menon, Cyrilla | menon@can-cia.org |
| Capsule Technologie | Burthey, Gretchen | gretchen@capsuletech.com |
| Cerner Corporation | Fackler, Jim | jfackler@cerner.com |
| CIMIT | Brown, Beverly<br>Crosby, Janice<br>Henderson, Jennifer<br>Whitehead, Susan | bbrown9@partners.org<br>jecrosby@partners.org<br>jahenderson@partners.org<br>swhitehead@partners.org |
| Datascope Corporation | Abramovich, Abe<br>Kaufman, Dean<br>Parsons, Samuel | abe_abramovich@datascope.com<br>dean_kaufman@datascope.com<br>sparsons@datascope.com |
| Datex-Ohmeda | Kosednar, Daniel | daniel.kosednar@med.ge.com |
| DocuSys, Inc. | Burrow, Michael | mburrow@docusys.net |
| Draeger Medical Systems, Inc. | Fuchs, Ken<br>Wallroth, Carl | ken.fuchs@draeger.com<br>Beate.Moeller@draeger.com |
| Duke University Medical Center | Weitzner, Stanley | weitz001@mc.duke.edu |
| Epic Systems Corporation | Abbott, Joe<br>Utley, Spencer | jabbott@epicsystems.com<br>sutley@epicsystems.com |
| Ethicon Endo-Surgery, Inc. | Charak, Ken | kcharak@eesus.jnj.com |
| FDA | Callaghan, Jim<br>Carstensen, Peter<br>Fitzgerald, Brian<br>Graham, Ann<br>Husband, Michael<br>Jones, Paul<br>Lee, Thomas<br>Murray, John | jvc@cdrh.fda.gov<br>PBC@CDRH.FDA.GOV<br>bjf@cdrh.fda.gov<br>ann.graham@fda.hhs.gov<br>MJH@CDRH.FDA.GOV<br>PXJ@CDRH.FDA.GOV<br>trl@cdrh.fda.gov<br>john.murray@fda.hhs.gov |

| | | |
|---|---|---|
| FDA (continued) | Taylor, Al | alt@cdrh.fda.gov |
| | Weininger, Sandy | sxw@cdrh.fda.gov |
| Fremont Associates, LLC | Clarke, Duncan | dclarke@fremontassociates.com |
| GE Healthcare Technologies | Schissel, George | George.Schissel@med.ge.com |
| | Schluter, Paul | Paul.Schluter@med.ge.com |
| | Tissot, Kevin | kevin.tissot@med.ge.com |
| Geisinger Health System | Poler, S. Mark | m.poler@ieee.org |
| Georgetown University, ISIS Center | Lindisch, Dave | lindisch@isis.imac.georgetown.edu |
| Getinge USA, Inc. | Corriveau, Heidi | heidi.corriveau@getingeusa.com |
| | Militello, Bob | bob.militello@getingeusa.com |
| IBM | Perrera, Chris | perrera@us.ibm.com |
| IBM TJ Watson Research Center | Williams, Rose | rosemw@us.ibm.com |
| IEEE | Cooper, Todd | t.cooper@ieee.org |
| IXXAT, Inc. | Seitz, Bill | seitz@ixxat.com |
| Johns Hopkins University | Deguet, Anton | anton@cs.jhu.edu |
| | Kazanzides, Peter | pkaz@cs.jhu.edu |
| | LaMora, Andrew | alamora@cs.jhu.edu |
| Kaiser Permanente | Blasingame, Jon | Jon.Blasingame@kp.org |
| | Howse, John | JHowse6540@aol.com |
| | Judd, Thomas | tom.judd@kp.org |
| | Morris, Robert | robert.j.morris@kp.org |
| | Robkin, Michael | Michael.B.Robkin@kp.org |
| | Snyder, Bob | BobSnyder400@aol.com |
| | Zimmerman, Zachary | Zachary.Zimmerman@kp.org |
| Karl Storz, Inc. | Stiller, Heinz-Werner | heinz-werner.stiller@karlstorz.ch |
| LiveData, Inc. | Robbins, Jeffrey | jeffr@livedata.com |
| Massachusetts General Hospital | Goldman, Julian | jmgoldman@partners.org |
| | Schrenker, Rick | raschrenker@partners.org |
| Medtronic Emergency Response System | Peterson, Ken | ken.peterson@medtronic.com |
| Morgan State University | Bronner, LeeRoy | lbronner@comcast.net |
| National Institute of Standards & Technology | Feng, Shaw | feng@nist.gov |
| | Sriram, Ram | sriram@nist.gov |
| National Science Foundation | Gill, G. Helen | hgill@nsf.gov |
| Philips Medical Systems, Inc. | Matthews, Joel | joel.matthews@philips.com |
| | Osborn, David | d.g.osborn@ieee.org |

| | | |
|---|---|---|
| Tyco Healthcare, Inc. | Washington, Ebonia | Ebonia.Washington@tycohealthcare.com |
| University of Maryland Medical Center | Khan, Arif<br>George, Ivan | arkhan@UMM.edu<br>igeorge@smail.umaryland.edu |
| University of Utah Medical Center | Westenskow, Dwayne | drw@ee.utah.edu |
| U.S. Army Telemedicine & Advanced Technology Research Center | Curley, Kenneth<br><br>Marchessault, Ron | curley@tatrc.org<br><br>marchessault@TATRC.ORG |
| Vanderbilt University Medical Center | St. Jacques, Paul | paul.stjacques@vanderbilt.edu |
| Villanova University | Sloane, Elliot | ebsloane@ieee.org |

## APPENDIX E

## STA Focus Group on Developing Clinical Requirements for
## Plug-and-Play OR Medical Device Interoperability Standards
### Thursday from 5:30 – 7:00 P.M., Radisson Hotel

Dear STA meeting attendee,

As noted in the meeting program, there will be a STA-sponsored focus group on Thursday immediately preceding the reception. The purpose of the focus group is to gather clinical requirements for developing plug-and-play (PnP) medical device interoperability standards in the OR of the Future. The proposed standards could permit seamless connectivity of medical devices to allow data <u>communication</u> (e.g. remote data display, population of the electronic anesthesia record, etc.) and <u>control</u> of medical devices (e.g. control of infusion pumps from the anesthesia machine, implementation of "safety interlocks" to prevent intra-abdominal $CO_2$ insufflation if the HR and BP are unmonitored, etc.).

The unique challenge of this project is that we are striving to develop an interoperability infrastructure to enable innovation. Therefore, it is important to <u>define the high-level general system requirements</u> without getting bogged down in the details of technical specifications. Manufacturers need to know <u>what you want the system to do</u>, so that they can determine how to best provide the desired functionality. During the focus group session, we will begin by asking the audience for examples of connectivity that could a) solve current clinical problems, b) improve safety or efficiency, or c) enable innovative clinical systems of the future.

Questions to stimulate your thinking: *(Assume that there are no technical, economic, legal, or regulatory obstacles to deploying a comprehensive ORF PnP system.)*
1. What clinical challenges exist today that could be solved by the proposed system?
2. Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
3. How would this approach affect the practice environment, both clinically and from a business perspective?
4. What risks may be introduced by a PnP system, and how could they be mitigated?

As you identify clinical challenges, consider that solutions may include dedicated intraoperative high-reliability networks, inexpensive handheld remote controls, ubiquitous wireless data displays, and hot-swappable networked devices.

During the focus group session, we will generate a prioritized list of clinical challenges that may benefit from a PnP infrastructure. Subsequently, we will delve into the details of the clinical solutions to identify the high-level ORF PnP system requirements that are necessary to implement those solutions.

We look forward to seeing you at 5:30.

Julian M. Goldman, MD (Mass Gen Hosp/CIMIT)    julian@acmeanesthesia.com
Abe Abramovitch (Datascope)
Robert Tham, PhD (GE)
Rob Clark (Draeger)
John Robinson (Philips)

# APPENDIX F

## SAGES Focus Group on Developing Clinical Requirements for Plug-and-Play O.R. Medical Device Interoperability Standards

Friday, April 15, 2005, 12:00-2:00 PM, Room 307, Westin Diplomat Resort

This focus group is being held to gather clinical requirements for developing plug-and-play (PnP) medical device interoperability standards for the OR of the Future. The proposed standards could improve patient safety and operative efficiency by permitting seamless connectivity of medical devices to allow data <u>communication</u> (e.g. remote data display, population of the electronic medical record, etc.) and <u>control</u> of medical devices (e.g. control of OR table position, insufflators, light sources, ESU, implementation of "safety interlocks" to prevent intra-abdominal $CO_2$ insufflation if the HR and BP are unmonitored, etc.).

The unique challenge of this project is that we are striving to develop an information technology interoperability infrastructure to enable innovation. Therefore, it is important to <u>define the high-level general system requirements</u> without getting bogged down in the details of technical specifications. Manufacturers need to know <u>what you as surgeons want the system to do</u>, so that they can determine how to best provide the desired functionality. During the focus group session, we will begin by asking the audience for examples of connectivity that could a) solve current clinical problems, b) improve safety or efficiency, or c) enable innovative clinical systems of the future.

Questions to stimulate your thinking: *(Assume that there are no technical, economic, legal, or regulatory obstacles to deploying a comprehensive ORF PnP system.)*

1. What clinical challenges exist today that could be solved by the proposed system?
2. Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
3. How would this approach affect the practice environment, both clinically and from a business perspective?
4. What risks may be introduced by an ORF PnP system, and how could they be mitigated?

As you identify clinical challenges, consider that solutions may include dedicated intraoperative high-reliability networks, inexpensive (sterile) handheld remote controls, ubiquitous wireless data displays, and hot-swappable networked devices.

During today's session, we hope to generate a prioritized list of clinical challenges that may benefit from a PnP infrastructure. Subsequently, we will delve into the details of the clinical solutions to identify the high-level ORF PnP system requirements that are necessary to implement those solutions.

Members of the SAGES Technology Committee have already expressed enthusiasm and will be in attendance.

Julian M. Goldman, MD, P.I. (Mass General Hospital/CIMIT)      julian@acmeanesthesia.com
David W. Rattner, MD, SAGES President      president@sages.org

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# APPENDIX G

## AAMI Session on Developing Requirements for
## Plug-and-Play O.R. Medical Device Interoperability Standards
Saturday, May 14, 2005, 2:45-4:00 and 4:15-5:30

This session is being held to gather clinical engineering requirements for developing plug-and-play (PnP) medical device interoperability standards for the Operating Room of the Future (ORF). The ORF PnP program began in May 2004 with stakeholders from industry, clinical facilities, and Federal agencies. It was agreed that the first project would be to gather user requirements to ensure that subsequently developed standards would meet essential clinical requirements. This is the third such session – and the first dedicated to clinical engineering.

ORF PnP standards could improve patient safety and perioperative efficiency by permitting seamless connectivity of medical devices to allow data <u>communication</u> and device <u>control</u>.

| Examples of **COMMUNICATION:** | Examples of device **CONTROL:** |
|---|---|
| Data aggregation and display, remote data access, comprehensive population of the electronic medical record, etc. | Control of OR table position, insufflators, infusion pumps, light sources, ESU, etc. <br> "Safety interlocks", for example, to prevent intra-abdominal $CO_2$ insufflation if the HR and BP are unmonitored. |

A key challenge of this project is that we are striving to develop an information technology interoperability infrastructure to enable innovation. Therefore, it is important to <u>define high-level general system requirements</u> without getting bogged down in the details of technical specifications. Manufacturers need to know <u>what you as clinical engineers want the system to do</u>, so that they can determine how to best provide the desired functionality. During the focus group session, we will begin by asking the audience for examples of connectivity that could a) solve current problems, b) improve safety or efficiency, or c) enable innovative clinical systems of the future.

Questions to stimulate your thinking *(assume that there are no technical, economic, legal, or regulatory obstacles to deploying a comprehensive ORF PnP system)*:

1. What clinical challenges exist today that could be solved by the proposed system?
2. Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
3. How would this approach affect the practice environment, both clinically and from a business perspective?
4. What risks may be introduced by an ORF PnP system, and how could they be mitigated?

As you identify clinical challenges, consider that solutions may include dedicated intraoperative high-reliability networks, inexpensive (sterile) handheld remote controls, ubiquitous wireless data displays, and hot-swappable networked devices.

During today's sessions, we hope to generate a prioritized list of clinical engineering challenges that may benefit from a PnP infrastructure. Subsequently, we will delve into the details of the clinical solutions to identify the high-level ORF PnP system requirements that are necessary to implement those solutions.

Julian M. Goldman, MD, P.I. (Mass General Hospital/CIMIT), julian@acmeanesthesia.com
Jennifer L. Jackson (Assistant Director of Biomedical Engineering, Brigham and Woman's Hospital), jljackson@partners.org

Visit <u>www.ORFPnP.org</u>          © Julian Goldman 2005

Address http://orfpnp.org/

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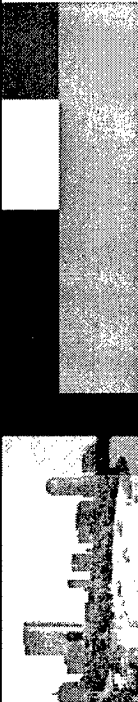
# Operating Room
# of the Future

Developing a Plug-and-Play Open Networking Standard

**Working Group Forums**

**CIMIT ORF Website**

**Past Meetings:**
May 2004
Nov 2004
STA Jan 2005

**Upcoming Events - HIMSS, AAMI**

**Plug-and-Play Interoperability for the Operating Room of the Future**
A multidisciplinary project to standardize communication and control of medical devices in the OR of the Future

The purpose of this website is to disseminate project information and to provide Working Group web forums. The Working Group forums provide an online community and are open to all project contributors. Please register and participate at www.orfpnp.org/workgroups/index.php.

The latest plenary meeting for this initiative took place on November 15-16, 2004, hosted by the FDA, and focused on assessing the regulatory framework and developing functional requirements for medical device plug-and-play standards.

A clinical requirements focus group session was held at the annual meeting of the Society for Technology in Anesthesia (STA) on January 13th. Check this website again soon for the results of that session and more upcoming events!

You can view the presentations from the May 2004 CIMIT/TATRC-sponsored kick-off symposium on the CIMIT/ORF website http://cimit.org/orfpnp.html.

Julian M. Goldman, MD
Massachusetts General Hospital
contact information

# APPENDIX I

## Plug-and-Play Connectivity for the Operating Room of the Future

Multidisciplinary project to develop standards for communication and control of medical devices in the O.R. of the Future

**php** creating communities

FAQ  Search  Memberlist  Usergroups
Profile  You have no new messages  Log out [ Julian Goldman ]

You last visited on 29 Sep 2004 09:36 am
The time now is 29 Sep 2004 12:12 pm
Plug-and-Play Connectivity for the Operating Room of the Future Forum Index

View posts since last visit
View your posts
View unanswered posts

### This Web site

| | Forum | Topics | Posts | Last Post |
|---|---|---|---|---|
| | **READ THIS FIRST!** You must register to vote or post comments | 1 | 1 | 25 Aug 2004 07:18 am Julian Goldman ⬆ |
| | **About the ORF PnP Project** History, goals and resources of ORF PnP project, including videos of May 2004 meeting. | 2 | 2 | 13 Sep 2004 03:24 pm Dan Donoff ⬆ |
| | **New User Questions** Need help using this forum? | 2 | 2 | 31 Jul 2004 09:10 pm Julian Goldman ⬆ |
| | **Feedback and Suggestions** | 1 | 1 | 15 Sep 2004 05:27 pm Todd Cooper ⬆ |

### ORF PnP Work Groups

| | Forum | Topics | Posts | Last Post |
|---|---|---|---|---|
| | **Nov 2004 Meeting Planning** Planning for November 2004 meeting at FDA in Rockville, Maryland | 3 | 4 | 14 Sep 2004 11:23 am Sue Whitehead ⬆ |
| | **Clinical Requirements (WG1)** Essential requirements and wish lists for ORF PnP connectivity. Working Group 1 Leader: John Howse, MD (Kaiser Permanente) Moderator John | 0 | 0 | No Posts |
| | **Regulatory (WG2)** Regulatory and legal issues related to medical device PnP connectivity. Working Group 2 Leaders: Mike Husband (FDA) and Jenn Henderson, JD, MPH (CIMIT) | 1 | 2 | 23 Sep 2004 02:47 pm Jennifer Henderson ⬆ |

Internet

# AAMI News

Association for the Advancement of Medical Instrumentation WWW.AAMI.ORG

## INSIDE...

## The Inside Word

*"In the end, the key measure of our growth and success in the industry is our people."*

> Brian Poplin
> Vice President,
> Clinical Technology Services
> ARAMARK Healthcare
> Management Services

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*Networking Standard Underway . . .*

# 'Plug and Play' Connectivity Initiative Launched

A broad consortium of medical interests has joined forces to develop an open networking standard for communication and control of medical devices.

Led by representatives from Boston-based Partners Healthcare and Kaiser Permanente in cooperation with the FDA, other health care professionals, and the U.S. Department of Defense, the group plans to incorporate existing interoperability work where possible and to develop new tools where necessary, in order to produce and implement an integrated "plug and play" medical device open networking standard within three years.

"The concept is that individual medical devices would be networked to allow the communication of data from one device to the other and the control of one medical device by another, as well as allowing the implementation of clinical rules or guidelines," explains Julian M. Goldman, MD, of Massachusetts General Hospital, principal

The "Operating Room of the Future" (ORF) at Massachusetts General Hospital

investigator for the project.

Such a standard would "help address the goal of integrating patient monitoring with clinical decision systems and electronic

---

*Industry Challenge Addressed . . .*

# Is Improved Medical Technology Worth the Cost?

Last fall, the nation's top economic guru told U.S. lawmakers that difficult choices lie ahead when it comes to balancing the need for budgetary restraint with the expense of new medical technology.

In economic outlook testimony, Federal Reserve Chairman Alan Greenspan cited recent-year outlays for Medicare and Medicaid that have grown faster than the national Gross Domestic Product (GDP), amounting to about 7% of GDP in 2003.

"In the context of an unprecedented increase in retirees, the need to make stark choices among budget priorities will again become pressing. Federally funding access to advances in medical technology, for example, likely will have to be weighed against other spending programs," said Greenspan.

Since that time, other economists have suggested that health spending is stifling job

growth and threatening to crowd out spending on education, housing, and infrastructure. In 2004, government estimates put the American health care bill at $1.79 trillion, or $6,167 per person— leaving some to ask: Are the health benefits of new medical technology worth the cost?

David Cutler

"Rising health costs are a challenge, but not a menace—much the way that high blood pressure is a problem to be addressed, but needn't be fatal," responds Harvard economist and health care expert David Cutler. Cutler suggests that lawmakers must come up with a "sound financing system"

# Networking Developed

medical records," according to Jennifer Jackson of Brigham & Women's Hospital. "Once the medical devices know how to talk to each other, then the devices will

**Jennifer Jackson**

also be able to communicate with networked information systems."

Some clinicians have long understood the need for connectivity of medical devices. Goldman offers an example from the operating room: During a laparoscopic procedure, the surgeon and the anesthesiologist must carefully orchestrate monitoring with insufflation of the abdomen. "Here's a teamwork issue that requires clear communication with complex activities that are interdependent—and if there's a

## The Operating Room of the Future

In August 2002, Massachusetts General Hospital opened a unique operating room suite designed to assess the effect of new technologies and new systems on the safety and efficiency of patient care.

The Operating Room of the Future (ORF) integrates the best ideas in patient flow management and state-of-the-art technology identified during a visioning and technology scavenging phase. Subsequently, teams of clinicians, engineers, technicians, architects, and administrators assured that the vision of the ORF was safely realized when opened for patient care.

Patients undergoing a variety of surgical procedures are cared for in the ORF. The majority of these procedures rely upon minimally invasive endoscopic techniques ("keyhole surgery"), for which the ORF has been optimized. The ORF is used on a daily basis and serves as an example of the effectiveness of multidisciplinary collaboration.

—Julian M. Goldman, MD

lapse anywhere along the way, it could cause a very serious patient problem."

The high-reliability information systems, advisory alarms, and safety interlocks of commercial aircraft are examples of what is needed in health care settings, according to Goldman. "In medicine, we have not had the opportunity to have creative, intelligent problem solvers try to apply some of the same ideas and solutions [used in aviation] to medicine because we don't have the infrastructure for them to create those things," he says.

Richard Schrenker, systems engineering manager for the Massachusetts General Hospital (MGH) Department of Biomedical Engineering, also believes that plug-and-play interoperability is long overdue. In the past, plug-and-play stan-

**Richard Schrenker**

dardization has "suffered from a Catch-22," says Schrenker: Manufacturers didn't develop standardized medical device communications because there was no demand for them; health care providers didn't demand them because they couldn't envision the problems the technology would address.

Schrenker hopes that projects like the "Operating Room of the Future" (ORF) at Massachusetts General will help to remedy this situation. In this "living laboratory," clinicians explore new technology platforms and systems of care for performing minimally invasive surgical procedures. The plug-and-play group convened two summits in 2004 to begin the process of developing technical and clinical requirements for a bus-independent standard for devices in the ORF.

Plug-and-play leaders are currently working through the Center for the Integration of Medicine and Innovative Technology (CIMIT), a Massachusetts-based non-profit consortium of institutions including Massachusetts General Hospital, Brigham and Women's Hospital, Massachusetts Institute of Technology, Draper Laboratory, Beth Israel Deaconess Medical Center, and Children's Hospital Boston. The consortium brings together clinicians, scientists, engineers, and industry to focus

on solutions to perplexing health care problems.

Industry partners, such as LiveData, Inc. of Cambridge, MA, see the potential of plug-and-play integration to "deliver functionality and efficiency" in a cost-effective format. "In the end, it's about providing solutions so that clinicians can do their jobs better—improving patient safety and patient care," says Phil Brzezinski, vice president of Health Care Systems for LiveData, maker of an electronic whiteboard being used to display patient data in the ORF.

According to Goldman, those who have previously tried to develop a standard failed to bring in several critically important stakeholders, such as the FDA, early on—making it difficult to achieve forward progress. This time around, representatives from the FDA's Center for Devices and Radiological Health (CDRH) have joined the discussion from the beginning.

"The FDA supports the development of a medical device control and communication open networking standard. This represents a new challenge with a need to assure patient safety while incorporating new technologies," explains Sandy Weininger, PhD, a senior biomedical engineer at CDRH.

According to **Sandy Weininger**
Weininger, FDA

has "partnered with the project team" to bring the concern for patient safety up front in the design process, to offer assistance in using a systematic development process, and to offer engineering expertise in relevant technologies—such as human factors, risk management, and systems engineering.

Organizers hope that demonstrating the potential of a plug-and-play standard in the ORF will be the breakthrough the technology has needed to gain acceptance. "The OR is just a starting point. There's a need for this in the intensive care unit, the emergency department, and home health care," says Goldman.

Once the plug-and-play concept is further developed and demonstrated, Schrenker believes its advantages will be obvious to the medical device industry. "When design engineers no longer

need to spend their time designing proprietary machine communications interfaces, more time can be devoted to extending functionality—which in our business translates into caring for patients," explains Schrenker. "Similarly, the cost of regulation should decrease, as reviewers will no longer need to evaluate each proprietary interface for safety and efficacy."

Jackson offers a hypothetical scenario: A physiological monitoring system installed at every ICU bedside in a hospital has integrated capnography licensed by the vendor from one manufacturer. Then, a nationwide change in practice calls for an updated capnography algorithm that is adopted by three other vendors—but not the hospital's vendor.

"Do I have to tell my physicians that they cannot comply with the new trend?" asks Jackson. "Or do I have to convince my administration to find the funding to re-standardize our bedside monitoring vendor because *one* parameter of our systems doesn't meet the specification anymore? It's a no-win situation for everyone in this group."

Instead, with a standard in place, "the users would get to choose the 'best of breed' algorithms that provide the best patient monitoring possible for a given procedure," says Jackson. "We could add or change parameters as needed without too much delay, and we could avoid introducing unneeded complexity to the system."

Jackson will moderate a plug-and-play session at the 2005 AAMI Annual Conference & Expo in Tampa (for more about the conference, see page 13).

"The project will be introduced in a short presentation, but then we want the audience members to break up into groups and come up with specifications," says Jackson. "This is a great opportunity for the AAMI audience because this community can fully appreciate the value that plug-and-play can bring to health care, *and* they also know what technical issues need to be addressed to create a stable system in a typically unstable environment. The new standard will not be prototyped by the end of the meeting, but we hope to walk away with a sound list of requirements from the medical devices technical community."

**Julian M. Goldman**

Goldman's group hopes to "show significant, tangible results within three years." Launched in May 2004, the plug-and-play project's first-year goals include identifying and convening key stakeholders, determining clinical requirements, refining the project plan, securing long-term funding, and establishing a plug-and-play lab that will explore different schemes for device connectivity.

The key here is to create an infrastructure," says Goldman, "and then let the creativity of clinicians and biomedical engineers take over to do the things that have needed to be done for a long time but were technically impossible to implement."

For more information on plug-and-play connectivity, visit the project's Web site at **www.orfpnp.org**, or contact Sue Whitehead at **swhitehead@ partners.org**. ∎

# Getting Connected to Save Lives

A patient undergoing surgery requires an x-ray, so the ventilator is stopped to prevent blurring of the image. Typically, this routine practice is uneventful. However, in a case published recently, another problem distracted the anesthesiologist, who then forgot to resume ventilation. The patient did not survive. A network infrastructure that would support innovative medical device safety "interlocks"—such as an "x-ray/ventilator synchronizer"—does not exist today. Many potential clinical hazards could be mitigated by implementing smart alarms, real-time decision support systems, and safety interlocks. Unfortunately, implementation of these solutions is not practical because medical device plug-and-play (PnP) connectivity standards do not exist today.

As you will see in this issue of *BI&T* (see page 188), the Operating Room of the Future (ORF) is a "living laboratory" where many aspects of perioperative health care delivery are being reassessed. During the past year, a multidisciplinary group has been laying the foundation for a framework of standards that would facilitate safe, reliable, medical device interoperability for data communication and device control. Identified as a core element of patient safety in the Massachusetts General Hospital ORF program, the ORF PnP project has attracted like-minded stakeholders from industry, the federal government, and hospital clinicians and clinical engineers, who agree that the absence of medical device PnP standards is an unacceptable barrier to innovation for safety and efficiency.

The ORF PnP project faces the challenge of developing a networking solution pathway to address identifiable clinical problems in current environments, and provide an innovation pathway for over-the-horizon medical device technologies and care patterns in the future. Data security, liability and regulatory issues, network performance monitoring, and interoperability with the broader health care enterprise must be considered. One goal, to paraphrase the Partners HealthCare Biomedical Engineering mission statement, is to bring us closer to the ideal state where "no patient is harmed by the application of a medical device."

*Julian M. Goldman*

Julian M. Goldman, MD
Department of Anesthesia and Critical Care
Massachusetts General Hospital/Harvard Medical School
Physician Advisor to Partners Biomedical Engineering
Boston, Massachusetts

# Inside the OR of the Future

Jody Lannen Brady

An anesthesiologist approaches the medicine cabinet in the surgical suite; the cabinet door senses her presence and automatically unlocks. When the anesthesiologist removes a drug, an alarm sounds to alert her that the patient in the room is allergic to that medication. After locating an appropriate alternative, the anesthesiologist shuts the cabinet, which locks itself and launches a self-inventory to record which drug has been removed and to send this information to the patient's medical record.

This so-called "smart cabinet" doesn't exist in operating rooms today, but it's well on its way—thanks to

a project aimed at redesigning the way that surgical care is delivered at U.S. hospitals. At Massachusetts General Hospital (MGH) in Boston, operating room 49 is better known as the "Operating Room of the Future" and it serves as the centerpiece of an ambitious research agenda that hopes to reduce medical errors, enhance patient comfort, increase staff satisfaction, and lower the cost of surgery.

The smart medical cabinet under development at Massachusetts General is just a small part of this larger vision, a collaborative effort between hospitals, non-profits, the Department of Defense and industry partners who believe that when it comes to performing surgery, U.S. hospitals need to rethink the way they do business.

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## Changing the Status Quo

Cables crisscrossing the surgical suite, equipment blocking the line of sight to monitors, nurses and doctors bumping elbows, delayed procedures, miscommunications leading to wrong-site surgery and other errors—problems such as these have plagued surgical teams and their patients for decades. Though hospitals have devoted resources to improving patient safety throughout the care process, surgical processes in the U.S. remain largely unchanged.

"It's very difficult, if not impossible, to introduce major change in an envi-ronment like this overnight," suggests Julian M. Goldman, MD, a principal anesthe-siologist with MGH's Ope-rating Room of the Future project. "If you introduce too many changes too quick-ly—new devices, modified processes—you can actually destabilize a system and introduce inefficiencies and unsafe conditions. Our program allows a controlled introduction of new ideas and new technology in a protected environment."

The Operating Room of the Future (ORF) project takes a two-pronged approach to the goal of improving the surgical status quo. First, funded research projects overseen by the Center for Integration of Medicine and Innovative Technology (CIMIT), a nonprofit con-sortium of hospitals and laboratories, tackle innovations such as the smart medical cabinet.

Perhaps more visible, though, is the "production environment"—the $2.5 million operating suite opened in Massachusetts General in August 2002—where refinements of work flow processes, ergonomic design, and state-of-the-art technology are put through their paces as patients undergo surgical procedures five days a week. In this "living laboratory," clinicians explore new technology platforms and systems of care for performing minimally invasive surgical procedures.

The team of clinicians, engineers, technicians, architects, and administrators involved in the selection and implementation of technology and processes "serves as an example of the effectiveness of multidisciplinary collaboration," according to Goldman. One member of that team, biomedical engineer Luis Melendez, remembers early round-table discussions of "what the room could do and what it shouldn't try to do."

"We don't simply look at new technology here," says Melendez, "we look at the setting and the use of that technology. Then we extract the concepts that work, so we'll be able to apply them in other settings."

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## Going with the Flow

Focusing on the setting in which surgery takes place has been a hallmark of ORF work to date. Modifying the operating room layout, placing equipment on ceiling-mounted booms, and inte-grating device controls have all contributed to eliminating much of the "downtime" of the tradi-tional surgical process.

In the standard Ame-rican operating room, pa-tients are checked in, hooked up to an array of monitors,
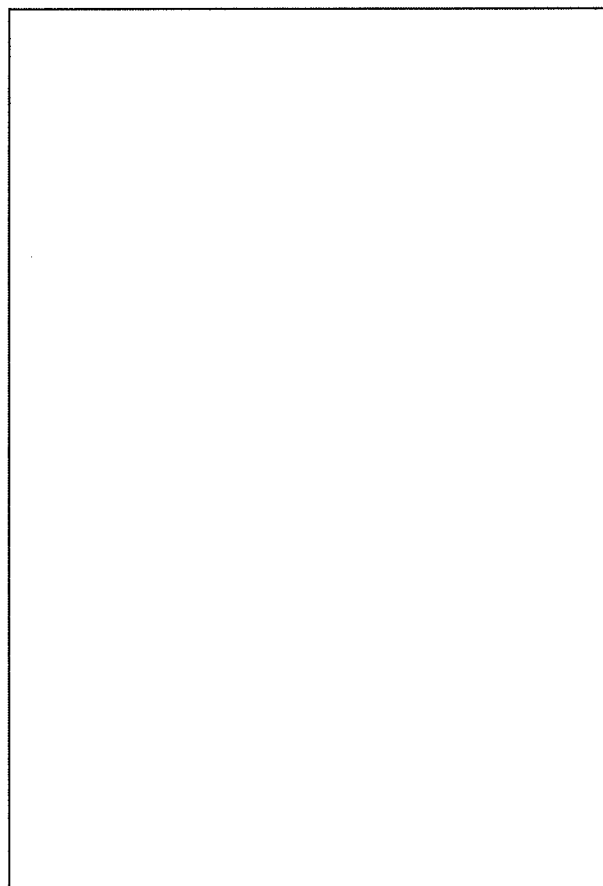
anesthetized, prepped for surgery, operated on, awakened, and prepared for transfer in a linear sequence. Before the next patient can be wheeled in, the anesthesia staff must escort the patient to the hospital's recovery area and the operating room must be cleaned again.

"The entire sequence is repeated throughout the day. A delay on the part of, say, the room-cleaning crew can slow down the progress of nursing, anesthesia, and surgery in this model," explains Marie Egan, RN, surgical nurse and project manager for ORF. "Each part is dependent on the previous process segment being completed, and very often people wait for one another to complete a portion of work before another can begin."

In contrast, the ORF was set up as a suite of linked rooms—including induction, operating, emergence, and control rooms. "We borrowed some elements of the European model of using an induction room to start anesthesia before moving the patient into the OR," explains Goldman. "Our goal was to move some of the linear processes to a parallel process."

In the ORF induction room, the anesthesia team prepares a patient for surgery at the same time that nursing prepares the OR. After surgery, the anesthesia team can monitor the patient in the emergence room—while the operating room is being cleaned and the next patient prepped in the induction room. Surgeons remain close at hand for consultation in the "control" room, where they can call the patient's family members, dictate notes, check e-mail, and review medical records between procedures.

"The time between cases—the 'non-operative time'—has been reduced," according to Egan. In this win-win scenario, the hospital books more procedures each day, the patient experiences a higher level of safety and comfort, and the staff works more efficiently.

### User-friendly Design

Key to moving patients seamlessly between the rooms of the operating suite is a MAQUET bed system from Getinge Group in Rastatt, Germany. This was selected during a "scavenging" phase, led by Nat Sims, MD, when ORF team members traveled around the country and abroad to identify "best of the best" surgical processes and equipment.

In the induction room, the patient is helped onto an operating table surface mounted on top of a trolley. After the patient has been prepped and anesthetized, the trolley is rolled into the operating room, where a pedestal base rises from the floor and lifts the table top high enough to allow the horseshoe-shaped trolley to be pulled away. After surgery, the table surface is replaced on the trolley and wheeled to the emergence room—eliminating the need to lift and move anesthetized patients.

> "Adapting technology means a higher level of troublshooting and a greater workload for clinical engineering..."
>
> —Luis Melendez

"When we move an anesthetized patient, it can cause hemodynamic instability in the patient—as well as back injuries for the staff," explains Goldman. "We wanted to eliminate lifting anesthetized patients and cut down on the rat's nest of cables—I usually call it 'macramé'—that has to be disconnected, untangled, and reattached each time a patient is moved."

When blood pressure cuffs, electrocardiogram leads, and pulse oximeters are disconnected in order to transport a patient in a traditional OR setup, the patient goes unmonitored while sensors are removed, leads unplugged, and cables moved out of the way.

Melendez and his team of biomedical engineers were called in to offer an alternative for the ORF: "Because I had served on the ORF design team, I understood the importance and subtleties of work flow issues when the physicians turned to me and asked, 'Luis, what can you do to help with this?'"

After evaluation and consultation with manufacturers of the equipment involved, the answer Melendez came up with was to mount the monitor rack and input module with all patient cables under the head of the operating table top. By integrating the monitor connections, only one cable needs to be unplugged when moving a patient between rooms of the operating suite.

This sort of creative solution, says Melendez, renders the system "easier for the end user." But, he adds a caution: The complex, integrated devices being added to surgical suites—such as control screens, video and audio switches, and embedded computers running WinOS—offer surgical advantages but also pose new challenges to biomedical engineering.

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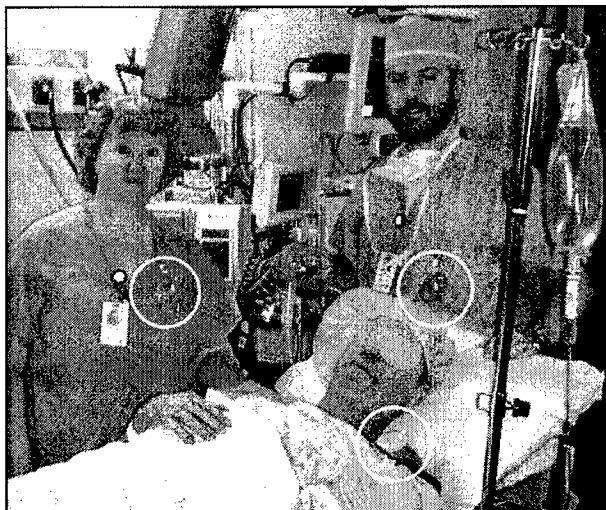
*Karen Kelly, RN, perioperative nurse, Julian Goldman, MD, anesthesiologist, and the patient are wearing IPS tags.*

troubleshooting and a greater workload for clinical engineering staff who need to understand the technology at a higher level than ever before," explains Melendez, who did a "fair amount of lobbying" in order to add a technical support position at MGH to deal with the increased demand.

### Advancing the State of the Art

When selecting technology, the ORF team looks for industry partners, rather than simply choosing a piece of equipment. The project's Web site (www.cimit.org/orfuture.html) outlines criteria for participation. Partners are expected to "share [the] vision that a clutter-free, integrated OR environment will improve patient safety and overall efficiencies"—as well as demonstrate a willingness to "commit the engineering resources required to achieving the project goals" and to "co-developing, with other project partners, an open architecture for equipment integration."

One of the partners selected, Radianse, Inc. of Lawrence, MA, provides the ORF with an indoor positioning solution (IPS) that tracks the locations of patients and staff.

"A key part of the project from the very beginning was designing an environment where outcomes could be measured," says Goldman. "And so a lot of attention was put into how to set up the system in order to easily record sufficient data to measure outcomes." The Radianse IPS offered the team a way to accurately and automatically

record the timing of procedures and movement of individuals through all rooms of the surgical suite.

For Radianse, the ORF project offered "an opportunity to tax our solution and prove it could accurately locate people and things—and do it quickly," explains John Pantano, vice president of marketing for Radianse. Among the benefits of working with the ORF team, Pantano cites the ability "to prove that not only was our system accurate even in very small spaces, but that our solution could indeed survive the challenges of a clinical environment."

Perioperative patients in the ORF wear radio frequency identification (RFID) tags that transmit to Local Area Network (LAN) receivers; the location is then calculated by software on a server and communicated to end users via Web applications. As a result of its ORF collaboration, the Radianse team has continued to refine its product. According to Pantano, the ORF team has influenced development of the system by pushing Radianse to enhance accuracy and to add intelligence to the system.

"That's why we just introduced an alerts application that allows hospitals to easily add automatic pages, e-mails, or other alerts based on the location of people, things, or both," says Pantano. The first example tested at Massachusetts General was to provide an objective measurement for start of anesthesia care. "When an anesthesiologist and a patient, each wearing a location tag, are in the induction room for a pre-defined amount of time, an association is made in the database to allow for automatic messages to the billing and documentation systems," explains Pantano.

Goldman sees the alert as just one example of the potential of IPS technology to "look at the context in which events occur." Making an "association"—such as recognizing the joint presence of the patient and anesthesiologist in the induction room—allows an event to be time-stamped in the patient's electronic medical record. The ORF team also seeks to mine context for "exceptions"—monitored events that fall outside a modeled process.

"Let's say that you know the next patient for surgery should have arrived at the preoperative check-in area by a certain time, but that person hasn't shown up yet. The system could automatically detect that the expected event hasn't occurred and notify appropriate personnel so that they take action," explains Goldman. "Automatic exception identification is very powerful. Just use your

imagination; this same concept could be applied to any event that can be monitored and that can be identified within the context of the perioperative profile."

## Lines of Communication

Facilitating open communication—whether between the surgical team members or between pieces of equipment—is an oft-repeated theme. When it comes to people, "physical proximity enhances communication" in the ORF, according to Egan.

In a standard OR configuration, the post-op patient is removed from the surgical suite and transported by anesthesia to a recovery area where a full report must be given to a nurse who has no prior knowledge of the patient. If there are follow-up questions or concerns, the appropriate staff member must be paged in the OR suite, where they have returned to start the next case.

By contrast, the nurse who takes care of post-op patients in the ORF suite is the same nurse who cared for the patient before surgery, and they already have patient history knowledge when they receive the report for anesthesia at the end of surgery.

"This means the report is shorter," says Egan. "The patient is then moved to an area about 20 feet from where the anesthesiologist is now caring for the next patient. The surgeon is also in the suite. If the nurse has any concerns, both surgery and anesthesia are immediately accessible."

Communication between devices employed in the OR suite is just as vital, and the ORF research team has made device integration one of their primary goals.

"Vendors integrate their own devices, but they have trouble being 'agnostic' about other suppliers' technologies," explains ORF anesthesiologist Warren Sandberg.

Existing anesthesia information management systems offer broader integration, but only on information that goes into the anesthesia record. The ORF team is collaborating with LiveData of Cambridge, MA, to create a real-time system that captures, integrates, and displays data from all the devices involved in patient care in the OR, including surgical equipment, hospital information, and patient order entry systems. Prototype implementation of LiveData's "electronic whiteboard" is scheduled for summer 2005.

"The goal of this project is to enhance situational awareness in the OR by providing total data integration in a single, large-format display," explains Sandberg.

The technological interoperability envisioned by the ORF team, however, goes far beyond the whiteboard display. The project's "plug-and-play" research team has joined forces with a broad consortium of medical interests to develop an open networking standard for communication and control of all medical devices. (See related "Plug-and-Play" article in this issue.)

"As opposed to this being a purely theoretical discussion, we're actually living the frustrations of not having a level of connectivity that would facilitate innovation," says Goldman.

In the ORF, a networked surgical system permits control of other surgical devices, but as a proprietary system it can only be used with a limited number of devices that have been approved by the manufacturer. Physiologic monitors and anesthesia equipment are not included in the network; a separate network connects physiologic monitors. A company such as LiveData must write custom software—at significant cost—to aggregate and display data from the disparate systems.

"We would like to use the aggregated data to implement real-time safety interlocks that could control medical devices, but the absence of open standards for medical device communication and control have delayed the implementation," ex-plains Goldman. "There-fore, the ORF system is an example of the potential of networked medical devices —but it's also an example of the frustrations with non-open, standards-based systems that don't quite provide us with what is needed."

The plug-and-play group, led by Goldman, convened two summits in 2004 to begin the process of developing technical and clinical requirements for a bus-independent standard with non-proprietary, open architecture that would allow all devices—regardless of manufacturer—to work together. Goldman's team hopes to have a plug-and-play standards framework for devices in place by 2008. (See www.orfpnp.org for more information.)

## The Future is Now

Massachusetts General isn't the only hospital looking to revolutionize the surgical suite. Across the country, other facilities have opened their own versions of the "operating room of the future," variously featuring robotics, telemedicine technology, design innovations, wireless tracking, voice recognition controls, and advanced 3-D imaging.

Back in August 2000, the University of Pittsburgh

Medical Center (UPMC) launched its version of the ORF, complete with robotic computer systems for speech recognition, endoscopic positioning, and minimally invasive microsurgery. Since then, UPMC has opened four additional state-of-the-art operating rooms and has added the da Vinci® Surgical System, which is manufactured by Intuitive Surgical of Sunnyvale, CA. The system integrates a surgical console, multiple robotic arms, and image processing.

"Our OR of the Future is here today," announced John W. Ashworth, chief executive officer for the University of Maryland Medical Center (UMMC) in June 2003, when UMMC opened its "Intelligent OR." Operating rooms at the 52,000-square-foot facility combine advanced video and other communications equipment with information technology. Among other state-of-the-art features, touch screen monitors in the operating room enable staff to instantly access diagnostic images and laboratory results.

What distinguishes the ORF at Massachusetts General from other cutting-edge surgical suites is the overarching emphasis on research. "The team's vision was not simply to build a high-tech OR environment," explains Goldman. "The intent was to use the operating room as the core component of a research program designed to explore new concepts, assess outcomes, and introduce the best ideas to other areas of the hospital and to the broader surgical community."

### The Results Are In

If success is measured by influence, then the ORF project has already begun to see results. Since organizing a day-long course covering the design, implementation, and results of the ORF effort at MGH, "interest and attendance have exceeded our expectations," says Sandberg.

"We have been contacted by several academic and community hospitals who want to learn about our experiences in order to translate ORF successes into their own settings," he explains. Adoption of parallel processing models of patient care such as the one developed and studied in the ORF is underway for selected types of surgery at several institutions, according to Sandberg.

"I think that the latency of these kinds of innovations are such that they take several years before you see them become mainstream, but we've certainly lit a fire under the national debate about innovation in perioperative care," adds Goldman, who expects to see more hospitals look to employ IPS for contextual analysis of events as exception alarms are developed commercially over the next few years.

Currently, ORF team members are preparing to enter a new phase, and they are engaged in evaluating all aspects of the project. To biomedical engineer Melendez, the project's greatest gains can't be viewed independently. "Any success we've seen," says Melendez, "is the cumulative success of a lot of little details." ∎

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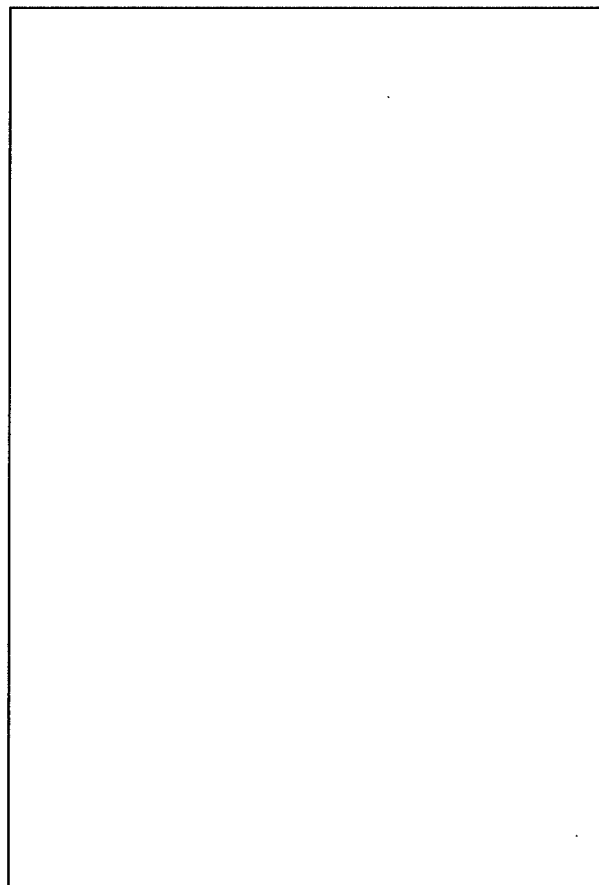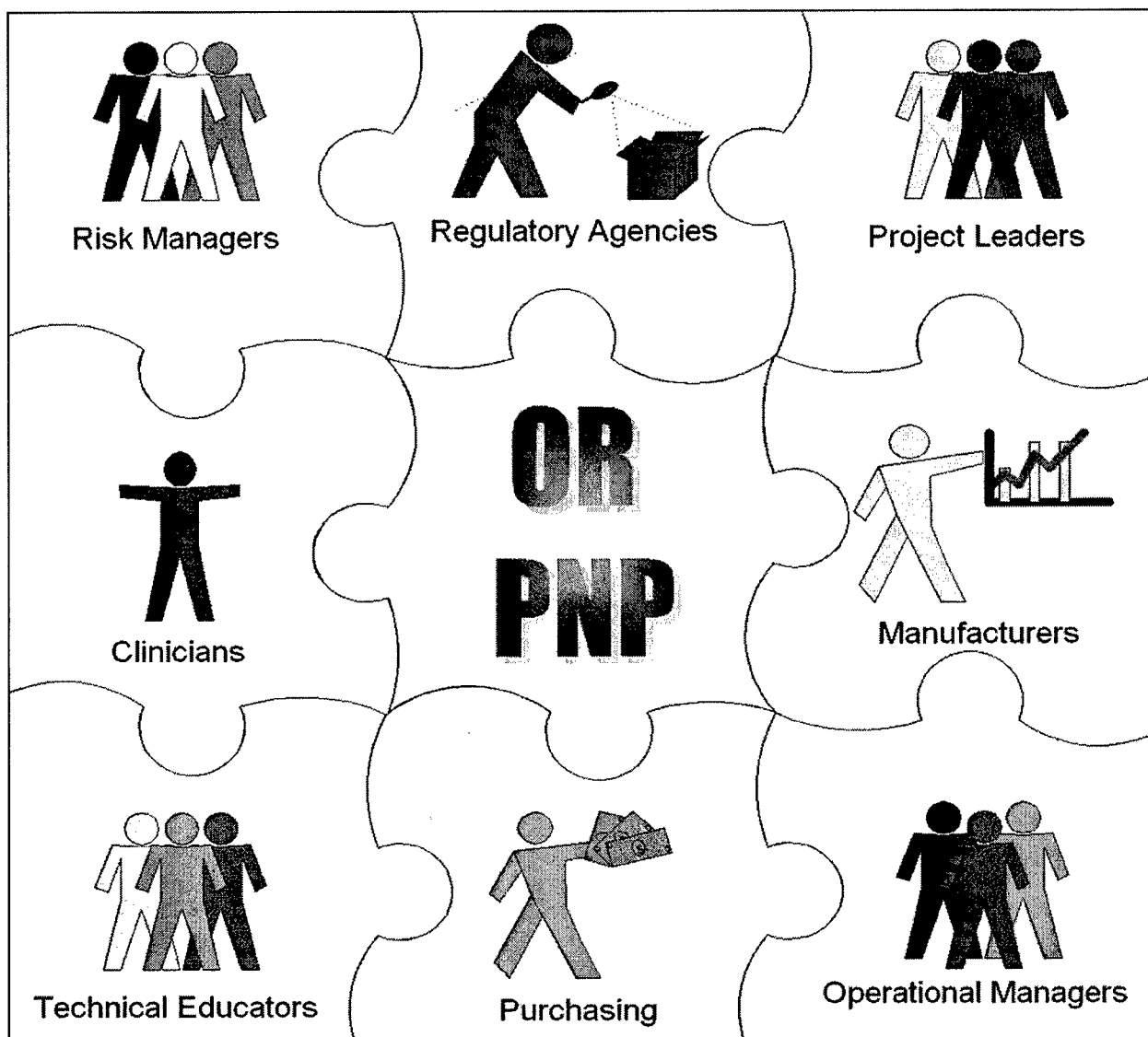
# Plug-and-Play in the Operating Room of the Future

Julian M. Goldman, Richard A. Schrenker, Jennifer L. Jackson, Susan F. Whitehead

How safe would a car be if key components, such as the brakes and cruise control, didn't work together? Can you imagine flying in an airplane that wouldn't provide a warning if the landing gear didn't deploy? Would you buy a new computer that would not allow you to upgrade the mouse, keyboard, or other peripheral components? Would your new "USB memory stick" be useful if it only worked with one brand of computer? The kinds of interoperable plug-and-play control and communication systems that we take for granted in automobiles and consumer electronics are lacking in operating rooms (OR) today.

Although intraoperative patient safety has improved significantly, the OR is still a complex and potentially hazardous environment where clinicians depend on teamwork and a patchwork of systems to mitigate hazards instead of using automated safety systems. Surprisingly, smart alarms and automated decision support tools are still absent from the clinical environment. Clinical engineers and clinicians have proposed innovative technical solutions to mitigate clinical hazards, but they cannot affordably implement novel solutions when real-time medical device data acquisition or control is required. Partly as a result of the lack of medical device interoperability, many self-evident improvements have been precluded, and safety

and economic benefits have not been realized.

Interoperability is not a new word to the health care industry. Just type "medical device interoperability" in the search field of an Internet search engine and watch the pages of hyperlinks that appear. Practitioners have commented on the need for medical device interoperability and have produced a wealth of guidance in the literature. The industry responded by providing products that sit on their proprietary architectures, and if you dig deep enough, you will find a few consultants or small technology firms that provide the products to tie it all together. The process of designing a wholly integrated system is still very fragmented for several reasons. For example:

- The diverse clinical groups have complex needs for knowledge-based decision support systems, automated record keeping and reporting, and for freely communicating devices that display a predefined set of parameters, given (1) the patient's history, (2) the protocol, and (3) the clinician's preference.
- The manufacturers recognize this opportunity and initially wanted to own as many pieces of this value chain as possible. Some will admit that they cannot successfully deliver the entire health care information and control system, but the limitations of corporate culture and the legacy of proprietary architecture keep development to a snail's pace.
- As of press time, the authors were not aware of a bottomless well of money or time to support the research and design needs for each institution to

create and support a system to meet their specific needs.

In an attempt to start addressing these issues, the program on Plug-and-Play (PnP) Interoperability of Medical Devices for the Operating Room of the Future provides the clinical and technical communities with an opportunity to finally take all of the pieces and put them together (see figure on page 195). The term "PnP" was adopted because the required technology infrastructure has many elements in common with the PnP approach used in other computer systems. First steps for the ORF PnP program include bringing the diverse stakeholders together in a series of forums, identifying the user needs and priorities, and building upon existing frameworks to develop the ORF PnP standard. A historical overview of medical device connectivity efforts clearly demonstrates the need for such a standard and provides the foundation for the ORF PnP project.

## Medical Device Connectivity History

As early as 1986, there were presentations at the AAMI Annual Meeting on microcomputer applications and maintenance. The potential to apply the new technology to point-of-care health care was quickly recognized, and early work commenced on IEEE 1073, which came to be known as the "Medical Information Bus" (MIB). Citations can be found on the web for some of this health care work going back to at least 1988.

### Why a Standard?

The demand, as present in 1988 as today, is to get data

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Rick Schrenker has worked in clinical engineering at Johns Hopkins Hospital and Massachusetts General Hospital, where he currently manages the Systems Engineering group in the Department of Biomedical Engineering. He holds a BS and MS in electrical engineering from Johns Hopkins University and has been active in IEEE 1073 standards activities since the mid '90s.

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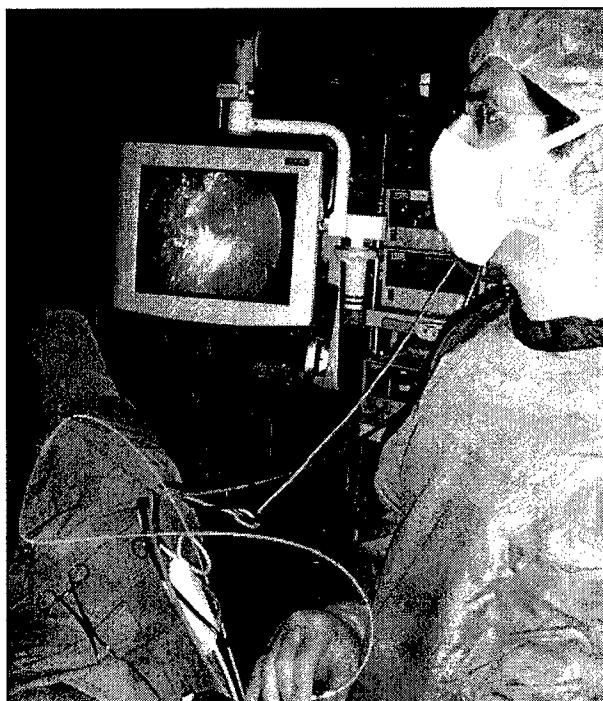


John Petrozza, MD, performing surgery with a KTP laser in the ORF.

from the instruments at the bedside into the bedside chart and the myriad of clinical information systems. The development of device interfaces is a known art that has long been reduced to practice. So why does the medical device community require its own standard?

By explicitly establishing attributes and behaviors for an interface, a medical device communications standard informs device and systems designers as to what they can expect of its features and performance. Where in the stack are errors trapped and how are they communicated? How are varying degrees of device complexity managed? How is remote control managed? What about alarms? Where standards are not present as guidance, the odds are small that independently working designers will address these and other design concerns in a similar fashion. The risk of creating a "Tower of Babel" is obvious; perhaps less so is the loss of potential value-add incurred by spending design cycles on developing interfaces rather than applications that improve patient care and/or safety.

Reportedly, there was initially great interest among a relatively large group of clinicians, as well as manufacturers, in getting a standard developed. But by the late 1980s, detailed focus on technical issues had

choked off clinical interest and soon thereafter manufacturer interest began to wane.

During the early 1990s, the defense industry spin-off LinkTech expressed interest in adapting its specialized communications products for the military to needs it perceived in the medical market. Review of the IEEE 1073 Web site shows meeting minutes going back to 1994 citing work involving LinkTech as well as members of the medical device and clinical engineering communities.

Coincident with the acceleration in device connectivity development was increased standards-related activity focused on hospital information systems. In 1996, Hewlett Packard formed the "Andover Working Group," a consortium focused on extending the work of Health Level 7 (HL7) by defining the content, structure, and communications infrastructure for specific messages. This group soon allied with 1073 to form a Special Interest Group for Medical Information Bus (MIB) within HL7. And in 1997, the first hospital adoption of 1073 was reported at McKay-Dee (Ogden, UT).

However, the lower layers were single solution, single sourced. The buzz was that they were too expensive for a medical device. In 1998, members of the 1073 General Committee developed a document describing the motivation for developing and adopting alternative lower layers. That same year, LinkTech closed its doors.

Remaining Andover Working Group members persevered and went on to develop new lower layers, demonstrating an implementation in February 1999 involving an infusion pump, patient monitor, and clinical information system workstation. That same day they announced the formation of a group intended to support the definition of new lower layers, forums for multi-vendor demonstrations, and participation in national and international standards organizations.

Since then, a core set of standards has been developed. Efforts directed at involvement and harmonization with standards groups resulted in establishment of connections with the European Committee for Standardization (CEN), International Organization for Standardization (ISO), Healthcare Informatics Standards Board (HISB), National Committee on Vital and Health Statistics (NCVHS), National Institute of Standards and Technology (NIST), and Healthcare Information & Management

| CAPABILITY | SAFETY | EFFICIENCY |
|---|:---:|:---:|
| Ubiquitous data acquisition and presentation | ✓ | ✓ |
| Decrease technology deployment barriers | | ✓ |
| Enable safety interlocks | ✓ | |
| Extend connectivity of health care environment | ✓ | ✓ |
| Enable decision support | ✓ | ✓ |
| Enable adaptive alarms, closed loop control, sensor networks | ✓ | ✓ |
| Hot-swappable networked medical devices | ✓ | ✓ |

**Table 1.** *Necessary attributes of an ORF PnP system.
Table © 2005 Julian M. Goldman, MD*

Systems Society (HIMSS). 1073 now also identifies itself as "x73," reflecting its connection to CEN, where 1073 is known as 11073. CEN and IEEE are sharing the standards development workload, effectively increasing the rate at which standards can be developed. Through HISB, x73 has become even more connected to the full set of U.S. informatics groups. In 2002, NCVHS included x73 with standards such as DICOM and HL7 in its recommendations to the U.S. Secretary of Health and Human Services regarding patient medical records information. And NIST has started collaborating with x73 to develop conformance tests.

### The ORF PnP Project—Vision, Scope, Timeline, Achievements to Date

Against this background, one of the authors (Goldman) launched the ORF PnP initiative as an offshoot of the Operating Room of the Future at Massachusetts General Hospital (see article titled "Inside the OR of the Future" in this issue). Tapping into interest from the ORF clinicians and the U.S. Army Telemedicine & Advanced Technology Research Center (TATRC) at the Department of Defense, Dr. Goldman worked with the Center for Integration of Medicine and Innovative Technology (CIMIT) to plan a forum for bringing together the diverse group of stakeholders to explore their interest in achieving a standard for interoperability of medical devices in the OR. The result was a unique

symposium that was held in May 2004 at CIMIT in Cambridge, MA.

The May kick-off symposium, jointly sponsored by TATRC and CIMIT, met its objective of convening for the first time a diverse group of stakeholders (84 attendees) that included clinical users (Kaiser Permanente, Partners Healthcare, and others), biomedical engineers, medical device manufacturers and other companies, federal regulatory staff, and standards experts. FDA announced its commitment to the PnP process, opening the door for dialogue about new paradigms for regulatory evaluation and validation. There was a broad consensus among the participants to launch a PnP initiative and a strong commitment to participate, moving the perception of PnP standards development from stagnant to inevitable.

The core team created a vehicle for communication through an ORF PnP Web site and online open forums for discussion. Four areas were identified for development within working groups:
- WG1 clinical requirements
- WG2 legal/regulatory
- WG3 communication architecture
- WG4 user interface requirements

Working Group leaders are experts recruited from among the May participants. The distribution list for information about the PnP initiative was expanded as a result of contacts developed through the May attendees. The FDA offered to host a second PnP meeting so that regulatory issues could be more thoroughly explored with increased FDA participation.

The two-day November meeting at FDA moved the ORF PnP standardization effort to the next level by broadening the base of participation, assessing the regulatory framework via open interchange with FDA staff, and beginning the process of defining clinical requirements and user interface requirements. The 75 attendees, many of whom were new participants, included representatives of 22 companies, Kaiser Permanente, clinicians, 10 FDA staff (three speakers), and staff from TATRC, the National Science Foundation, and NIST, broadening the interest from federal agencies. FDA and TATRC affirmed their continuing commitment to the ORF PnP process, and there was ongoing strong support from Kaiser Permanente and industry. The initial exploratory work on defining clinical requirements clarified how extensive the requirements effort will be. Standards

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*Some of the device-specific interface cables required to deploy the commercial electronic anesthesia medical record (EMR) system in use at the Massachusetts General Hospital. (Photo inspired by W. Driscoll.)*

experts identified related standards already in process (e.g. IEEE 1073) that are relevant to ORF PnP, setting the stage for future collaboration.

The level of interest and commitment expressed to date by the stakeholders affirms that the time is right for proceeding with the definition of requirements and eventually with the development of a bus-independent consensus standard for ORF device interoperability. In January, the first of several planned focus group sessions on clinical requirements for PnP in the OR was held at the Society for Technology in Anesthesia (STA) meeting. The 50 session attendees enthusiastically contributed pages of ideas related to requirements for PnP and obstacles to achieving it, and the Society affirmed an ongoing commitment to the project.

## Upcoming Plans

Similar sessions to gather clinical requirements are planned for surgeons (at the Society of American Gastrointestinal and Endoscopic Surgeons annual meeting in April 2005) and nursing staff in the next several months, as well as at the AAMI annual conference in May 2005. We are capturing and refining this process from one session to the next. The ORF PnP program was presented at the HIMSS annual meeting in February, and efforts are underway to collaborate with the HIMSS initiative on Integrating the Healthcare Enterprise (IHE) and with the Office of the National Coordinator for Health Information Technology, headed by Dr. David Brailer.

## The Need for Clinical Engineering

At AAMI 2005 in Tampa, FL, the health care technology management community will have the opportunity to participate in one of these forums, representing several stakeholders in this process. In the health care setting, the project leader, the operational manager, the technical educator, and the risk manager all have a unique perspective and can provide the input necessary to define what the "ideal" system should look like and how it should behave.

Those acting as the local project leader for medical technology can provide input about how to bring this new PnP technology into the health care setting. For example, in new construction or new replacements, how is the PnP framework incorporated with a new system install?

The operational manager can comment on what should be required for regular maintenance and repair. How should the system react if a single device needs to be removed for repair? Should the system send a notification to alert the designated person about the failure? For specific systems, are there certain errors that you want to know about before a real failure occurs? Can you define those errors or give examples?

Whether the training is scheduled or on the spot, there is a need to effectively demonstrate and teach how to use a specific device or system. Two contributions that the technical educator can make are a review of the user interfaces that are best designed to minimize the learning curve and a description of the feedback that will be useful for improving an on-site training program.

## URLs of Cited Activities and Agencies

www.orfpnp.org
www.cimit.org/orfuture.html
www.ncvhs.hhs.gov
www.nist.gov
www.himss.org/
www.ieee1073.org
www.cenorm.be/cenorm.index.htm
www.iso.org
www.aami.org
HISB: www.ansi.org/standards_activities/standards_boards_panels/hisb/overview.aspx?menuid=3

*Minimally invasive surgery is aided by monitor placement in the MGH/CIMIT OR of the Future.*

The risk manager must evaluate systems for patient and clinician safety controls; with interoperability, one needs to understand how one integrated device's failure will affect the entire system. When incidents need to be investigated, the system or device can supply some information or tools, but those features still need to be designed. Will a simple event log listing all time-stamped button presses and transmitted messages suffice? Or does the investigator need a more visual playback? And what are the implications for operating a set of devices in a coordinated fashion during a code?

Each member in the health care technology management matrix has an experience or an idea that can be shared, and these ideas are highly sought after. Contributions from these valuable stakeholders—the project leader, the operational manager, the technical educator, and the risk manager—can make a tremendous impact on the final definition of the ORF PnP standard. This model provides a forum not only to influence by contributing, but also to be influenced by the contributions of allied professionals.

### The Time is Now

While earlier efforts at moving toward interoperability of medical devices were indicative of the clinical interest at the time, they sank in a morass of detail and proprietary interest—in some ways, a matter of "too little, too soon." Today we are seeing a convergence of many factors that are key to success—improved technology, more open-sourcing, technically savvy clinicians, and a willingness on the part of regulatory authorities to consider new validation paradigms. Manufacturers who are involved in the PnP program are clearly saying that what they need to move forward is an understanding of the demand for interoperability and of the clinical user requirements and functional specs for how it will work in practice. There is a huge interest in developing use cases that can lead to the identification and development of standards. We believe we have a reasonable and realistic way to respond to that request, and we need your help.

The opportunity for clinical engineers, biomedical engineers, operational managers, risk managers, and others in our community to be heard is at hand. Participating in the definition of requirements will enable all of us to be part of the solution when it comes. And there is little doubt that it is coming. ■

## In the Next Issue of *BI&T*...

✓ Fundamentals of... Clinical Lab Analyzers

✓ FDA's Critical Path Initiative

✓ Medical Terminology Part 2

✓ Verification Checks and PMs

✓ Cell Phone Use in Hospitals